

REMARKS

Claim Objections

Claim 68 has been object to because of a punctuation error. The Applicant has amended claim 68 to address the punctuation error, and withdrawal of the objection to claim 68 is respectfully requested.

Drawings

The drawings have been objected to for failure to include a reference sign associated with the molded spacer 10 set forth in the specification. The Applicant submits herewith a replacement drawings sheet including amended Figure 1. The amended version of Figure 1 now includes a reference number 10 that designates the spacer body. The Applicant therefore respectfully requests withdrawal of the objection to the drawings.

Claim Rejections – 35 USC §103

Claims 3, 15, 28-31, 35, 36, 38, 42, 46, 57, 58, 80-85 and 88 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,019,793 to Perren in view of U.S. Patent No. 6,281,262 to Shikinami. Additionally, claims 2, 43, 44, 50 and 104 have been rejected as being unpatentable over Perren in view of Shikinami and in further view of U.S. Patent No. 5,290,289 to Sanders et al., and claims 39-41, 59-61, 63, 64, 67-72 and 79 have been rejected as being unpatentable over Perren in view of Shikinami and in further view of U.S. Patent No. 6,491,724 to Ferree.

Claim Amendments

Independent claim 28 has been amended to include the subject matter of dependent claims 2 and to improve its form, and independent claim 80 has been amended to depend from independent claim 28. Additionally, claims 2-4 and 85-88 have been cancelled without prejudice for possible submission in a continuing application. New claims 105-109 have been added. Support for new claims 105-109 is found, for example, at page 8, lines 4-10 and 18-20; as-filed claim 2; and Figures 1-4 of the as-filed application.

Arguments in Support of Patentability

The seminal case directed to application of 35 U.S.C. §103 is Graham v. John Deere, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). From this case, four familiar factual inquiries have resulted. The first three, determining the scope and content of the prior art, ascertaining differences between the prior art and the claims at issue and resolving the level of ordinary skill in the pertinent art, are directed to the evaluation of prior art relative to the claims of the pending application. The fourth factual inquiry is directed to evaluating evidence of secondary considerations. See Manual of Patent Examining Procedure (MPEP) §2141. While performing this analysis, the cited references must be considered in their entirety, i.e., as a whole, including portions that would lead away from the claimed invention. See MPEP §2141.02 (citing W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)). From these inquiries, the initial burden is on the Examiner to establish a *prima facie* case of obviousness.

Additionally, the Supreme Court in the recent decision of KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, 127 S.Ct. 1727, 167 L.Ed.2d 705 (U.S. 2007), citing In Re Kahn, 441 F.3d 977, 988 (CA Fed. 2006), stated:

[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

KSR, 82 USPQ2d at 1396.

For at least the reasons set forth below, the Applicant submits that the pending claims are patentable over the cited references.

Independent Claim 28 and Dependent Claims 15, 29-36, 38-41, 46-49, 50-58, 80-83 and 105

Independent claim 28 has been rejected as being unpatentable over Perren in view of Shikinami. Specifically, the Office Action asserts that Perren discloses each of the elements and features recited in independent claim 28 except for the material being a shape-memory polymeric material, but nevertheless asserts that “Shikinami discloses a shape-memory polymeric material”,

and that [i]t would have been obvious . . . to construct the device of Perren having at least the polymeric shape-memory material of Shikinami to permit further biocompatibility and function in use as a spinal implant”. (See page 3, line 1 to page 4, line 16). The Applicant respectfully disagrees with these assertions for at least the following reasons.

Independent claim 28 has been amended to include the subject matter of dependent claim 2 and to improve its form. Support for the amendments to independent claim 28 is found, for example, at page 8, lines 4-10 and 18-20; as-filed claim 2; and Figures 1-4 of the as-filed application. Independent claim 28 now recites, among other elements and features, “a cylindrical body extending along a vertical axis and composed of a shape memory polymeric material and comprising a cylindrical-shaped peripheral sidewall extending about said vertical axis and defining an interior cavity and vertebral bearing surfaces defined by opposite end surfaces of the cylindrical-shaped peripheral sidewall”, “wherein the peripheral sidewall in the first configuration has a first lateral dimension and the opposite end surfaces of the peripheral sidewall each define a first bearing surface area”, and “wherein the peripheral sidewall in the second configuration has a second lateral dimension greater than the first lateral dimension and the opposite end surfaces of the peripheral sidewall each define a second bearing surface area significantly greater than the first bearing surface area”.

The Office Action makes reference to Figures 4 and 5 of Perren in support of the rejection of independent claim 28. Additionally, the Office Action appears to assert that upper and lower plates 1 of the Perren device define a peripheral sidewall. Even assuming arguendo that the upper and lower plates 1 in the insertion configuration illustrated in Figure 4 could somehow be construed to constitute “a cylindrical-shaped peripheral side wall” including “opposite end surfaces”, these opposite end surfaces do not constitute “vertebral bearing surfaces”. Instead, the upper and lower surfaces 3 of the plates 1 are the surfaces which constitute vertebral bearing surfaces, and the end surfaces of the plates 1 do not in any way engage the adjacent vertebra and therefore do not constitute vertebral bearing surfaces.

Moreover, neither of the opposite end surfaces of the plates 1 “define a first bearing surface area” when in a first configuration, and “a second bearing surface area significantly greater than the first bearing surface area” when in a second configuration. Indeed, as shown in

Figures 4 and 5, while the upper and lower plates 1 change shape between the insertion configuration illustrated in Figure 4 and the expanded configuration illustrated in Figure 5, the surface area defined by the end surfaces of the upper and lower plates 1 remains constant and unchanged. In other words, although the overall shape or profile of the upper and lower plates 1 changes between the insertion and expanded configurations, such change in shape/profile clearly does not result in increase in the surface area defined by the end surfaces of the plates 1. Indeed, in order for the surface area defined by the end surfaces of the plates to increase, the overall thickness of the peripheral sidewall must also increase. As illustrated in Figures 4 and 5, the thickness of the plates 1 remains uniform and constant as the Perren device is transitioned between the insertion and expanded configurations. Therefore, the surface area defined by the end surfaces of the plates 1 also remains uniform and constant, and does not result in an increased surface area. Furthermore, even assuming arguendo that the insertion configuration of the Perren device illustrated in Figure 4 could be construed as comprising “a cylindrical body”, the expanded configuration of the device illustrated in Figure 5 has a rectangular configuration, which is in no way cylindrical in nature.

Additionally, as pointed out in detail in the Applicant’s response to the previous Office Action, Shikinami likewise fails to disclose each of the elements and features recited in independent claims 28, and Shikinami therefore fails to satisfy the shortcomings of Perren.

Since Perren and Shikinami fail to disclose or suggest each of the elements and features recited in independent claim 28, the Applicant submits that independent claim 28 is patentable over these references, and withdrawal of the rejection of independent claim 28 is requested.

Claims 15, 29-36, 38-41, 46-49, 50-58, 80-83 and 105 depend either directly or indirectly from independent claim 28 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 28. However, further reasons support the patentability of these claims.

For example, claim 50 recites that “the first configuration of the body comprises a compressed flattened configuration, and wherein the second configuration of the body comprises an expanded cylindrical configuration”. With regard to Perren, even assuming arguendo that the first configuration illustrated in Figure 4 could be construed as a “cylindrical configuration”, and

that the second configuration illustrated in Figure 5 could be construed as a “flattened configuration”, claim 50 recites first and second configurations that are directly contrary to the first and second configurations illustrated in Figures 4 and 5 of Perren. Specifically, although the first configuration illustrated in Figure 4 of Perren could arguably be construed as a “compressed” configuration, the first configuration has a circular shape, and clearly does not constitute “a compressed flattened configuration”, as recited in claim 50. Moreover, although the second configuration illustrated in Figure 5 of Perren could arguably be construed as an “expanded” configuration, the second configuration has a rectangular shape, and clearly does not constitute “an expanded cylindrical configuration”, as recited in claim 50. Moreover, given the structural features and operational aspects of the Perren device, one of ordinary skill in the art would not reverse the shapes/profiles of the first and second configurations, for to do so would frustrate the principles of operation and other operational characteristics of the Perren device.

Additionally, claim 105 recites that “the cylindrical-shaped peripheral sidewall extends continuously about said vertical axis”. However, the Perren device clearly does not disclose or suggest the inclusion of cylindrical-shaped peripheral sidewall that extends continuously about a vertical axis, as recited in claim 105.

Independent Claim 42 and Dependent Claims 43, 44, 59-61, 63-72, 77-79, 104, 106 and 107

Independent claim 42 has been rejected as being unpatentable over Perren in view of Shikinami. Specifically, the Office Action asserts that Perren discloses each of the elements and features recited in independent claim 42 except for the material being a shape-memory polymeric material, but asserts that “Shikinami discloses a shape-memory polymeric material”, and that [i]t would have been obvious . . . to construct the device of Perren having at least the polymeric shape-memory material of Shikinami to permit further biocompatibility and function in use as a spinal implant”. (See page 3, line 1 to page 4, line 16). The Applicant respectfully disagrees with these assertions for at least the following reasons.

Independent claim 42 recites, among other elements and features, “a body composed of a shape memory polymeric material and comprising a peripheral sidewall defining an interior cavity and vertebral bearing surfaces at opposite ends of the peripheral sidewall”, the body having “a first configuration . . . wherein said body upon absorption of thermal energy expands

to a second configuration”, “wherein the peripheral sidewall in the first configuration has a first lateral dimension and a first sidewall thickness defining a first cross-sectional area”, and “wherein the peripheral sidewall in the second configuration has a second lateral dimension greater than the first lateral dimension and a second sidewall thickness greater than the first sidewall thickness, the second sidewall thickness defining a second cross-sectional area significantly greater than the first cross-sectional area”. (Emphasis added).

As an initial matter, the Applicant notes that no grounds or bases of rejection are set forth in the Office Action as to how the Perren device includes a peripheral side wall in first configuration that has “a first sidewall thickness defining a first cross-sectional area”, and a second configuration that has “a second sidewall thickness greater than the first sidewall thickness”, and with “the second sidewall thickness defining a second cross-sectional area significantly greater than the first cross-sectional area”. Indeed, the Office Action does not set forth any rationale or reasoning as to how a peripheral sidewall of the Perren device has a varying sidewall thickness, much less “a first sidewall thickness” in a first configuration and “a second sidewall thickness” in a second configuration that is “greater than the first sidewall thickness”. The Applicant notes that the Office Action does not use or in any way refer to the terms “sidewall thickness” or “cross-sectional area”. For this reason alone, a prima facie case of obviousness has not been established with regard to independent claim 42.

Moreover, the Office Action makes reference to Figures 4 and 5 of Perren in support of the rejection of independent claim 42. Additionally, the Office Action appears to assert that upper and lower plates 1 of the Perren device define a peripheral sidewall. Even assuming arguendo that the upper and lower plates 1 could somehow be construed to constitute “a peripheral side wall”, neither of the plates 1 has “a first sidewall thickness defining a first cross-sectional area”, and a second configuration that has “a second sidewall thickness greater than the first sidewall thickness”, and with “the second sidewall thickness defining a second cross-sectional area significantly greater than the first cross-sectional area”. Indeed, as shown in Figures 4 and 5, while the upper and lower plates 1 change shape between the insertion configuration illustrated in Figure 4 and the expanded configuration illustrated in Figure 5, the thickness and cross-sectional area of the upper and lower plates 1 remain unchanged. In other

words, although the overall shape or profile of the upper and lower plates 1 changes between the insertion and expanded configurations, such change in shape/profile clearly does not result in a greater thickness of the plates 1 or a greater cross-sectional area defined by the thickness of the plates 1.

Additionally, as pointed out in detail in the Applicant's response to the previous Office Action, Shikinami likewise fails to disclose each of the elements and features recited in independent claims 42, and Shikinami therefore fails to satisfy the shortcomings of Perren.

Since Perren and Shikinami fail to disclose or suggest each of the elements and features recited in independent claim 42, the Applicant submits that independent claim 42 is patentable over these references, and withdrawal of the rejection of independent claim 42 is respectfully requested.

Claims 43, 44, 59-61, 63-72, 77-79, 104, 106 and 107 depend either directly or indirectly from independent claim 42 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 42. However, further reasons support the patentability of these claims.

For example, claim 43 recites that "the body is provided in an original configuration having an original cross-sectional area that is greater than the first cross-sectional area", and claim 44 further recites that "the original cross-sectional area is greater than the second cross-sectional area". As indicated above with regard to independent claim 42, the side wall thickness and the cross-sectional area defined by the thickness of the upper and lower plates 1 of the Perren device is constant and does not in any way change from a first configuration to an expanded second configuration, much less from an original configuration having "an original cross-sectional area that is greater than the first cross-sectional area" defined by a first implant configuration, or an original cross-sectional area that is "greater than the second cross-sectional area" defined by a second expanded configuration. Instead, the cross-sectional area of the upper and lower plates is constant and non-changing. Accordingly, a *prima facie* case of obviousness has not been established with regard to claims 43 and 44.

Additionally, claim 68 recites that "the body has a height selected to be between about 3 and about 20 mm", and claim 69 further recites that "the body has a height selected to be

between about 4 and about 14 mm”. The Applicant notes that no grounds or bases of rejection are set forth in the Office Action in support of the rejection of claims 68 and 69. (See page 7, lines 1-10). Accordingly, a *prima facie* case of obviousness has not been established with regard to claims 68 and 69.

Furthermore, claim 104 recites that “the first configuration of the body comprises a compressed flattened configuration, and wherein the second configuration of the body comprises an expanded cylindrical configuration”. With regard to Perren, even assuming arguendo that the first configuration illustrated in Figure 4 could be construed as a “cylindrical configuration”, and that the second configuration illustrated in Figure 5 could be construed as a “flattened configuration”, claim 104 recites first and second configurations that are directly contrary to the first and second configurations illustrated in Figures 4 and 5 of Perren. Specifically, although the first configuration illustrated in Figure 4 of Perren could arguably be construed as a “compressed” configuration, the first configuration has a circular shape, and clearly does not constitute “a compressed flattened configuration”, as recited in claim 104. Moreover, although the second configuration illustrated in Figure 5 of Perren could arguably be construed as an “expanded” configuration, the second configuration has a rectangular shape, and clearly does not constitute “an expanded cylindrical configuration”, as recited in claim 104. Moreover, given the structural features and operational aspects of the Perren device, one of ordinary skill in the art would not reverse the shapes/profiles of the first and second configurations, for to do so would frustrate the principles of operation and other operational characteristics of the Perren device.

Moreover, claim 106 recites that “said body comprises a cylindrical body extending along a vertical axis, and wherein the peripheral sidewall has a cylindrical-shape extending about said vertical axis”, and is submitted to be patentable for reasons similar to those set forth above in support of the patentability of independent claim 28. Claim 107 further recites that “said cylindrical-shaped peripheral sidewall extends continuously about said vertical axis”, and is submitted to be patentable for reasons similar to those set forth above in support of the patentability of claim 105.

Independent Claim 84 and Dependent Claims 108 and 109

Independent claim 84 has been rejected as being unpatentable over Perren in view of Shikinami. Specifically, the Office Action admits that that Perren and Shikinami disclose the claimed invention except for having multiple expandable spacers. Nevertheless, the Office Action asserts that “use of an additional or a second spacer having it’s own expanded conditions or specific materials would have been obvious . . . since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art”. (See page 6, lines 9-17; emphasis added). The Applicant respectfully disagrees with this assertion.

As an initial matter, independent claim 84 recites elements and features similar to those recited in independent claim 28 which, as indicated above, is submitted to be patentable over the Perren/Shikinami combination. Moreover, even assuming arguendo that it would have been obvious to use an additional spacer, independent claim 84 recites more than just adding a duplicate spacer. Instead, independent claim 84 recite a first expandable spacer having a first configuration and an expanded second configuration, and a second expandable spacer having a third configuration sized substantially the same as the first configuration of the first spacer and wherein “the second spacer expands to a fourth configuration and is sized differently than the first spacer in the second configuration”.

Even assuming arguendo that one of ordinary skill in the art would be motivated to provide first and second expandable spacers, one of ordinary skill in the art would not be motivated to provide the second spacer with an expanded configuration (i.e., a forth configuration) that is sized differently than an expanded configuration (i.e., a second configuration) of the first spacer. Instead, even if one of ordinary skill in the art would be motivated to provide first and second spacers, such spacers would logically be provided with identical expanded configurations, and not with expanded configurations having different sizes. Additionally, the grounds set forth in the Office Action that “mere duplication of the essential working parts of a device involves only routine skill in the art” (see page 6, lines 9-17) is misplaced. Indeed, providing a second expandable spacer having an expanded configuration that is sized differently than the expanded configuration of a first expandable spacer is not “a mere

duplication” of parts, but instead constitute providing first and second spacers that each have different and unique structural characteristics that together treat a particular vertebral defect.

For at least the reasons set forth above, the Applicant submits that independent claim 84 is patentable over Shikinami, and withdrawal of the rejection of independent claim 84 is respectfully requested.

Claims 108 and 109 depend either directly or indirectly from independent claim 84 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 84. However, further reasons support the patentability of these claims.

For example, claim 108 recites features similar to those recited in independent claim 28, which are submitted to be patentable for reasons similar to those set forth above in support of the patentability of independent claim 28. Claim 109 further recites that “said cylindrical-shaped peripheral sidewall extends continuously about said vertical axis”, and is submitted to be patentable for reasons similar to those set forth above in support of the patentability of claim 105.

CONCLUSION

In view of the foregoing remarks and amendments, it is respectfully submitted that the Applicant's application is in condition for allowance with pending claims 15, 28-36, 38-44, 46-61, 63-72, 77-84 and 104-109.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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